Form FFCL-W. Worksheet for Designing Individual Field Trials under Aquaflor® INAD #12-061

INSTRUCTIONS

1. This Worksheet is an aid for Investigators preparing to use Aquaflor® under INAD #12-061. The information solicited is required to comply with FDA regulations. Before beginning, Investigators should have carefully read through the entire Study Protocol. Fill-in this Worksheet as completely as possible.

2. Investigators should sign and archive the original, and send a copy of the Worksheet to the Monitor for review and signature. The Monitor should then forward the signed Worksheet to the Study Director at the AADAP Office. The Study Director will also review the Worksheet, assign the Worksheet a Study Number, and then provide the Investigator and Monitor with the Study Number and approval to proceed with Aquaflor® treatment.

SITE INFORMATION

Facility			
Address			
Investigator			
Reporting individual (if not investigator)			
Phone		**FAX**	

LOBSTER CULTURE AND DRUG TREATMENT INFORMATION

Lobster species/stock to be treated			
Lobster disease to be treated			
Number of lobsters per rearing unit (indicate tank, raceway, pond, or pound)			
Number of units to be treated		**Number of untreated control units**	
Number of lobsters per pound		**Estimated total weight of lobsters treated (lb or kg)**	
Intended florfenicol dose (i.e., 10 or 15 mg florfenicol per kg body weight per day)			
Projected % body weight to be fed			
Planned duration of drug treatment (days)		**10**	
Total medicated feed needed (lbs or Kg)			
Planned grams of Aquaflor® pre-mix in feed			
Anticipated treatment dates (start/end)			
Feed type (manufacturer/moist vs dry/size) for treatments and controls (identify both if different)			

Form FFCL-W. Worksheet for Designing Field Trials (cont.)

STUDY DESIGN: Variable(s) to be tested: (See Sections VIII - XIII in Study Protocol). Describe in detail the purpose of the clinical trial (hypothesis), the number of experimental units, florfenicol dosage, the number of lobsters, and the disease to be treated. Study designs must be carefully prepared and lend themselves to rigorous evaluation. If more space is required to describe study design, title additional page(s) "Study Design" and attach to this Worksheet.

(type here)

Study designed by _____

DISPOSITION OF TREATED LOBSTERS (Food Safety Considerations):

_____ Estimated time (days) from last treatment day to first possible harvest for human consumption

Check applicable box(es):

☐ 10 mg florfenicol per kg BW per day for 10 days; 21-day withdrawal period

☐ 15 mg florfenicol per kg BW per day for 10 days; 28-day withdrawal period

☐ Investigator or alternate shall initial here to indicate awareness that lobster disposition must be in compliance with FDA-mandated withdrawal times as described in Section XV. of the Study Protocol.

WORKER SAFETY CONSIDERATIONS:

☐ Initial here to indicate that all personnel handling drug have read Material Safety Data Sheet for Aquaflor® and are aware of SAFETY precautions to be taken when handling medicated feed.

Initials are those of: _____
(Print Name)

Date prepared _____ Investigator _____

Date reviewed _____ Monitor _____

FORM FFCL-1. Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

INSTRUCTIONS

1. Investigator must fill out Form FFCL-1 **immediately** upon receipt of Aquaflor® premix or Aquaflor® medicated-feed.
2. Investigator should keep the original on file, and send one copy to the Study Monitor for review.
3. Within 10 days of receipt, the Study Monitor should send a copy to the AADAP Office.
4. **Note:** Both Investigator and Study Monitor should sign and date Form FFCL-1.

The sponsor, U.S. Fish and Wildlife Service, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetics Act. The following information is submitted in triplicate:

Name of Drug	Aquaflor®	INAD Number	12-061
Proposed Use of Drug	Treatment of certain bacterial diseases that occur in lobsters		
Date of CVM Authorization Letter	September 15, 2011		
Date of Drug Receipt		**Amount of Drug Received**	
Drug Lot Number		**Trial Number**	
Name of Investigator			
Address of Investigator			
Location of Trial			
Pivotal Study	Yes	Non-pivotal Study	---
Approximate Number of Treated Animals		**Approximate Number of Control Animals**	
Number of Animals Used Previously[1]			
Study Protocol Number	12-061		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum daily dose and duration	15 mg florfenicol/kg body weight per day for 10 consecutive days		
Methods(s) of Administration	Medicated-feed		
Withdrawal Period	21 days at 10 mg/kg dose, 28 days at 15 mg/kg dose		

[1] **To be filled out by the AADAP Office**

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Date Reviewed: _____ **Sponsor:** _____

FORM FFCL-1a. Report on Receipt of Drug - Guide For Reporting Investigational New Animal Drug Shipments For Poikilothermic Food Animals
(For Feed Manufacturers)

Department of Health and Human Services
Center for Veterinary Medicine, HFV-199
Food and Drug Administration
7500 Standish Place
Rockville, Maryland 20855

Date: _____
INAD No: 12-061
Name of Drug: Aquaflor®
Trial Number: NA
Lot Number: _____

The sponsor, U.S. Fish and Wildlife Service, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetic Act. The following information is submitted in triplicate (original and two copies):

Name of Drug: Aquaflor® (florfenicol)

Proposed Use of Drug: Treatment of certain bacterial diseases that occur in lobsters

Date of CVM Authorization Letter: September 15, 2011

Date Drug Received: _____

Amount of Drug Received: _____

Name of Feed Manufacturer: _____
(typed or printed)

Address of Feed Manufacturer: _____

_____

Pivotal (intended for support of NADA) X and/or nonpivotal X study

For Study Information and Details Refer to Study Number: _____

Protocol (*pivotal studies only*): Date submitted to CVM and/or number: NA

Maximum dose and duration: 15 mg florfenicol/kg body weight per day for 10 consecutive days

Method(s) of Administration: Medicated-feed

Withdrawl Period: 21 days at 10 mg/kg dose; 28 days at 15 mg/kg dose

If the investigation is discontinued, the Food and Drug Administration will be notified, giving the reason and disposition of the drug.

Feed Manufacturer (Authorized Representative): _____
Signature and Date

Form FFCL-2a. Chemical Use Log for Clinical Field Trials Using Aquaflor® Under INAD #12-061 (Aquaflor® Premix)

Instructions:
1. Initiate Form 2 immediately upon receipt of Aquaflor® premix.
2. Each lot number of Aquaflor® premix may be used for multiple treatment regimes.
3. A signed copy of Form 2 should be sent to the Study Monitor at the end of the Study Year.
4. Original Form 2 should be archived at the investigating facility.

Quantity on Hand From Previous Page (lbs): _____ Facility: _____ Reporting Individual: _____

Aquaflor® Premix Lot Number	Date Received	Amount Received (g)	Date Used	Study Number	Aquaflor® Premix Used for Treatment (g)	Aquaflor® Premix Shipped[1] (g)	Aquaflor® Premix Disposal[2] (g)	Aquaflor® Premix On-hand (g)	Inventoried by (initials)

[1] Unused Aquaflor® Premix that is shipped to another facility participating in Aquaflor® INAD #XX-XXX (Note: Aquaflor® Premix can only be shipped to another facility with prior authorization by the AADAP Office).

[2] Unused Aquaflor® Premix that is disposed of by burial or in a landfill.

Investigator: _____
Signature and Date

Study Monitor: _____
Signature and Date

Form FFCL-2b. Chemical Use Log for Clinical Field Trials Using Aquaflor® Under INAD #12-061 (Aquaflor® Medicated-feed)

Instructions:
1. Initiate Form 2 immediately upon receipt of Aquaflor® medicated-feed.
2. Each lot number of Aquaflor® medicated-feed should be used for a single treatment regime.
3. A signed copy of Form 2 should be sent to the Study Monitor at the end of the Study Year.
4. Original Form 2 should be archived at the investigating facility.

Quantity on Hand From Previous Page (lbs): _____ **Facility:** _____ **Reporting Individual:** _____

Aquaflor® Medicated-feed Lot Number	Date Received	Amount Received (lbs)	Dates Used	Study Number	Aquaflor® Medicated-feed Used for Teatment (lbs)	Aquaflor® Medicated-feed Shipped[1] (lbs)	Aquaflor® Medicated-feed Disposal[2] (lbs)	Aquaflor® Medicated-feed On-hand (lbs)	Inventoried by (initials)

[1] Unused Aquaflor® medicated-feed that is shipped to another facility participating in Aquaflor® INAD XX-XXX (Note: Aquaflor® medicated-feed can only be shipped to another facility with prior authorization by the AADAP Office).

[2] Unused Aquaflor® medicated-feed that is disposed of by burial or in a landfill.

Investigator: _____
Signature and Date

Study Monitor: _____
Signature and Date

Form FFCL-2FM. Chemical Use Log for Clinical Field Trials Using Aquaflor® Medicated-Feed Under INAD #12-061 - Aquaflor® Premix

(For Use by Feed Manufacturers)

Instructions:

1. Initiate Form 2 immediately upon receipt of Aquaflor® premix.
2. Each lot number of Aquaflor® premix may be used for multiple treatment regimes.
3. A signed copy of all Form 2s should be sent to the AADAP Office at the end of each calendar year.
4. Original Form 2s should be archived at the feed manufacturing facility.

Aquaflor® Premix Lot Number	Date Received	Amount Received (g)	Date Used	Study Number	Aquaflor® Premix Used for Feed Preparation (g)	Aquaflor® Premix On-hand (g)	Inventoried by (initials)

Feed Manufacturer (Authorized Representative): _____

Signature and Date

Form FFCL-3. Diagnosis, Treatment, and Mortality Record for Clinical Field Trials Using Aquaflor® Medicated-feed under INAD #12-061

Instructions:

1. Complete this report no later than 10 days after completion of the 21-day post-treatment observation period. Attach lab reports and other information.
2. Investigators should sign and archive the original, and send a copy of the form to the Monitor for review and signature. Within 10 days of receipt, the Monitor should send a copy to the Study Director at the AADAP Office for inclusion in the permanent file.

SITE INFORMATION

Facility	
Reporting Individual	

LOBSTER CULTURE AND DRUG TREATMENT INFORMATION

Lobster species/stock treated			
Lobster disease treated			
Number of lobsters per rearing unit (indicate tank, raceway, pond, or pound)			
Number of treated units		Number of control units	
Number of lobsters per pound		Total weight of lobsters treated (lb or kg)	
Florfenicol dosage (i.e., 10 or 15 mg per kg body weight per day)		Treatment duration	10 days
Feed rate (% BW/day)		Total medicated feed fed (lb or kg)	
Aquaflor® lot number		Aquaflor® used to prepare medicated feed (g)	
Feed Manufacturer			
Feed type and crumble/pellet size			
Feeding method (hand, auto) and frequency			
Date treatment started		Date treatment ended	

WATER QUALITY PARAMETERS

Ave pre-treatment temp (°F)		Dissolved oxygen (mg/L)	
Ave treatment temp (°F)		pH	
Ave post-treatment temp (°F)		Hardness - $CaCO_3$ (mg/L)	

Form FFCL-3. Daily Mortality Record

INSTRUCTIONS

Enter today's date (mo/day) and water temp (°F.). Enter the rearing unit numbers at the head of each column for each test or control unit in the study. Enter "T" if the unit is designated in the study to receive treatment. Enter "C" if the unit is designated as an untreated control unit. Also enter the number of lobsters in each rearing unit at the start of the study. Enter each days total mortality for each unit in the proper column. Use additional copies of this form for additional rearing units or additional days of observation.

			Rearing Unit #	Rearing Unit #	Rearing Unit #	Rearing Unit #	Rearing Unit #	Rearing Unit #	
		T or C							
		# Fish							
Day	Date	Water Temp	Mortality #	Mortality #	Mortality #	Mortality #	Mortality #	Mortality #	Observer Initials
Pre-treatment Period									
10									
9									
8									
7									
6									
5									
4									
3									
2									
1									
Treatment Period									
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

Form FFCL-3. Daily Mortality Record

INSTRUCTIONS

Enter today's date (mo/day) and water temp (°F.). Enter the rearing unit numbers at the head of each column for each test or control unit in the study. Enter "T" if the unit is designated in the study to receive treatment. Enter "C" if the unit is designated as an untreated control unit. Also enter the number of lobsters in each rearing unit at the start of the study. Enter each days total mortality for each unit in the proper column. Use additional copies of this form for additional rearing units or additional days of observation.

			Rearing Unit #	Rearing Unit #	Rearing Unit #	Rearing Unit #	Rearing Unit #	Rearing Unit #	
		T or C							
		# Fish							
Day	Date	Water Temp	Mortality #	Mortality #	Mortality #	Mortality #	Mortality #	Mortality #	Observer Initials
Post-treatment period									
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
21									

Results: Explain outcome of treatment. Describe in detail exactly how treatment worked. Was treatment successful? If not, why not? Attach pathology reports; Both Pre-and Post-Treatment.

Toxicity Observations: (Report any negative reaction of lobsters; did treatment harm lobsters?)

Drug Discharge Resulting from Treatment: Calculate actual FFC drug level in facility discharge resulting from treatments. Use Addendum 2: Discharge Worksheet for calculations and attach completed Discharge Worksheet to this form. Also indicate method of disposal (if any) of FFC-bearing solid wastes.

Observed Withdrawal Period: (Investigator should initial the appropriate box below)

☐ 21 day withdrawal period [treatment at 10 mg florfenicol/kg body weight per day]

☐ 28 day withdrawal period [treatment at 15 mg florfenicol/kg body weight per day]

Estimated number of days between last treatment and first availability of lobsters for human consumption (ensure this time period meets the withdrawal period). _____

Disposition of Unused or Spoiled Aquaflor® Medicated-Feed:

_____ **Negative Report:** Aquaflor® medicated-feed was not used at this facility under this Study Protocol Number. (Investigator should initial for negative reports.)

Date prepared _____ Investigator _____

Date reviewed _____ Monitor _____